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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,239	11/03/2003	Andrew S. Pekosz	60005161-0114	3764

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EXAMINER

SALVOZA, M FRANCO G

ART UNIT PAPER NUMBER

1648

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/700,239

Applicant(s)

PEKOSZ ET AL.

Examiner

M. Franco Salvoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

1. Claims 1-25 are pending and under consideration.

Claim Rejections - 35 USC § 102

MAINTAINED

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-16, 19-23, and 25 were rejected under 102(b) as anticipated by U.S. Patent No. 6,270,958 to Olivo et al.

Applicant argues that in light of the amendment to claim 10 reciting “wherein the expression of the polypeptide can occur in the absence of a viral nucleocapsid protein” the rejection is traversed, since Olivo et al. discloses “wherein the antigenome comprises a reporter gene and ‘one or more nucleotide sequences encoding each of the nucleocapsid proteins of the negative-strand RNA virus which are necessary and sufficient for the replication of minigenome RNA or miniantigenome RNA synthesized by the DNA-dependent RNA polymerase.’” Since claim 11 of Olivo et al. requires the encoding and expression of nucleocapsid proteins, it does not anticipate claim 10.

Applicant’s arguments are considered but found unpersuasive. Nakagawa et al. is cited in support of Olivo et al. to disclose which nucleocapsid proteins are necessary and sufficient for replication and which ones are not. Nakagawa et al. teaches that PB2 is not required for

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replication or transcription of uncapped poly-A RNA, and that despite the absence of influenza viral protein PB2, PB1 and PA alone can support and are sufficient for viral RNA synthesis in replication of the genome (p. 6390).

While the nucleoprotein (NP) gene is present in Nakagawa et al.'s plasmids, to give the term "viral nucleocapsid protein" its broadest reasonable interpretation would encompass PB2 as a viral nucleocapsid protein (or, a protein located in the viral nucleocapsid, defined broadly as "the nucleic acid and surrounding protein coat in a virus" (See Merriam-Webster's definition enclosed)).

Therefore, Nakagawa et al.'s recitation that replication or transcription of the viral genome can occur in the absence of one specific viral nucleocapsid protein (PB2) teaches that expression of the polypeptide can occur in the absence of "a" viral nucleocapsid protein and anticipate claim 11, reciting "in which expression of the polypeptide can occur in the absence of a viral nucleocapsid protein."

The rejection is maintained for reasons of record.

Claim Rejections - 35 USC § 103

MAINTAINED

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 3, 6, 7, 8 and 9 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Olivo et al. Claims 2 and 18 were inadvertently excluded. No new issues are raised by their inclusion in this rejection. The two claims recite the respective methods wherein the segmented negative strand RNA virus is selected from the group consisting of influenza A virus, influenza B virus, and influenza C virus. Therefore, claims 1, 2, 3, 6, 7, 8, 9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olivo et al. and maintained.

Applicant argues that the PTO has not demonstrated any of the three requirements for establishing prima facie obviousness, that the PTO has not shown that Olivo et al. teaches or suggest every claim element, that the PTO has not shown that Olivo et al. presents any suggestion or motivation to modify the reference, and the PTO has not established a reasonable expectation of success for detection of a segmented negative strand RNA virus.

Applicant's arguments are considered but found unpersuasive. For clarity, the rejection will be elaborated in more detail.

See the teachings of Olivo et al. above (supported by Nakagawa et al. and Merriam-Webster). Olivo et al. also teaches that the method can be used to detect influenza viruses (column 1, line 25).

Olivo et al. does not teach a cell comprising a recombinant RNA molecule with RNA-dependent RNA polymerase that comprises the reporter gene.

One of ordinary skill in the art at the time the invention was made would have been motivated to use RNA as an alternative construct in addition to the RNA-dependent RNA polymerase to express the reporter gene in order to detect negative strand RNA viruses.

One of ordinary skill in the art at time the invention was made would have had a

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reasonable expectation of success for using RNA as a construct due to common nucleic acid structures and techniques known in the art.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary, and the rejection is maintained for reasons of record.

Claims 2, 17, 18, and 24 were previously rejected under 103(a) as being unpatentable over Olivo et al. and Neumann et al. Claims 2, 17 and 18 are withdrawn from this rejection, leaving the rejection of claim 24 maintained under 103(a) as being unpatentable over Olivo et al. and Neumann et al.

Applicant argues that the PTO has not shown prima facie obviousness for this claim since, because neither Olivo et al. nor Neumann et al., singly or in combination, teaches or suggests each and every claim element. Applicant also argues that Olivo et al. does not teach the method wherein expression of the polypeptide depends on the presence in the cell of an RNA-dependent RNA polymerase of the virus and wherein the expression of the polypeptide can occur in the absence of a viral nucleocapsid protein, and that Neumann et al. is directed to a RNA polymerase I transcription system for influenza viral cDNA flanked by a rDNA promoter. Therefore, neither Olivo et al. and Neumann et al., considered either singly or in combination, establish prima facie obviousness for claim 24.

Applicant's arguments are considered but found unpersuasive. For clarity, the rejection will be elaborated in more detail.

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Claim 24 recites wherein the genetically engineered vertebrate cell is a transiently transfected genetically engineered vertebrate cell.

See the teachings of Olivo et al. above (supported by Nakagawa et al. and Merriam-Webster) as to claims 10-16, 19-23, and 25 as well as the Olivo et al. 103 rejection as to claims 1, 2, 3, 6, 7, 8, 9 and 18. Olivo et al. also discloses the method for stably infected cells (column 10, line 40).

Olivo et al. does not teach the method for transiently infected cells.

Neumann et al. teaches transcription of pseudo-viral influenza cDNA molecules in transiently transfected cells in vivo by RNA polymerase (p. 477).

One of ordinary skill in the art would have been motivated to use the method of Olivo et al. in the transiently transfected cells of Neumann et al. because Neumann et al. teaches successful transcription of pseudo-viral cDNA molecules in vivo in such cells.

One of ordinary skill in the art would have had a reasonable expectation of success for using the method of Olivo et al. and the transiently transfected cells of Neumann et al. because both teach expression of negative strand RNA molecules in transfected cells.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary, and the rejection is maintained for reasons of record.

Claims 4 and 5 were previously rejected under 103(a) as being unpatentable over Olivo et al. and Fodor et al. Claim 17 was inadvertently excluded. No new issues are raised by its inclusion in this rejection. Therefore, claims 4, 5 and 17 are rejected under 103(a) as being unpatentable over Olivo et al. and Fodor et al.

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Applicant argues that the PTO has not shown prima facie obviousness for these claims because neither Olivo et al. nor Fodor et al., viewed singly or in combination, teach or suggest every claim element, and further, that neither singly or in combination teaches detection of influenza virus which involves the expression of a reporter gene polypeptide that depends on the presence in the cell of a viral RNA-dependent RNA polymerase and can occur in the absence of a viral nucleocapsid protein.

Applicant's arguments are considered but found unpersuasive. For clarity, the rejection will be elaborated in more detail.

Claim 4 recites the method wherein the artificial segment comprising the 5'UTR comprises the 5' UTR of the NP segment of an influenza virus; claim 5 recites the method wherein the 3' UTR of the artificial segment comprises the 3'UTR of the NP segment of an influenza A virus. Claim 17 recites the method of claim 11 wherein at least one of the 3'UTR and the 5'UTR is a UTR of the NP segment of an influenza A virus.

See the teachings of Olivo et al. above (supported by Nakagawa et al. and Merriam-Webster) as to claims 10-16, 19-23, and 25 as well as the Olivo et al. 103 rejection as to claims 1, 2, 3, 6, 7, 8, 9 and 18. Olivo et al. does not teach the use of the NP segment.

Fodor et al. teaches the use of the NP segment.

One of ordinary skill in the art would have been motivated to use the method of Olivo et al. with the NP segment of Fodor et al. because Fodor et al. teaches that the NP nucleoprotein is able to encapsidate in addition to replication and transcription in cells.

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One of ordinary skill in the art would have had a reasonable expectation of success for using the method of Olivo et al. and the NP segment of Fodor et al. since Olivo et al. and Fodor et al. both teach detection and expression of influenza viruses in cells.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary, and the rejection is maintained for reasons of record.

The rejection is maintained for reasons of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

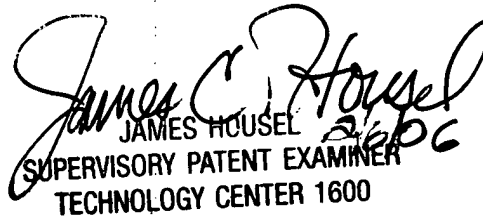
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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